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EXAMINER	
SISSON, BRADLEY L	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/355,705	KOSTER ET AL.
	Examiner	Art Unit
	Bradley L. Sisson	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-19,44-47,53-55 and 57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-19,44-47,53-55 and 57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

1. Acknowledgement is made of the amendment of 15 April 2003 whereby claims 5, 21, 48-51 and 56 have been canceled and claims 1, 4, 20, 23-25, and 57 were amended.

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 1-19, 44-47, and 53-56 of this application. In order for an application to be entitled to priority of an earlier filing date, the instant application and each and every application in the chain upon which the claim for priority is based, must meet *inter alia* the requirements under 35 USC 112, first paragraph, as it relates to the written description requirement. *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d 1961, 1966. Claims 1-4, 6-19, 44-47, and 53-56 are drawn to generic composition claims that encompass virtually any and all biopolymers, and in independent claims, encompass virtually and nucleic acid as well as antibodies. The specification defines the nucleic acid in terms of how it is to function, as it does enzymes, antibodies, etc., yet it does not provide an adequate written description of just what these compounds are. *Enzo Biochem Inc. v. Gen-Probe Inc.* (Fed. Cir. 01-0123; April 2002). It is not enough that alternative embodiments may be obvious in light of the disclosure when coupled with what is known in the art, the specification still must adequately

describe the invention. *Lockwood*. Accordingly, and in the absence of convincing evidence to the contrary, the claim for priority is not granted.

Response to argument

2. Acknowledgement is made of applicants traversal of the foregoing holding on the claim for priority. While applicant asserts that they disagree with the Examiner's conclusion (response of 14 April 2003 at page 4), no evidence has been presented which overcomes the holding. Accordingly, and in the absence of convincing evidence to the contrary, the subject application is not entitled to the benefit of the 04 February 1997 filing date of the provisional application.

Specification

At page 28 of the response applicant directs attention to page 14, lines 3-5, of the disclosure, and reproduces a portion of text. A review of said page 14, lines 3-5, does not yield the recited passage. It would appear that applicant was referring to page 13, last three lines, of the original specification. While applicant has included a catchall phrase that all documents have been incorporated by reference, such statement has not been found to fulfill the requirements of a proper incorporation by reference. Aside from indicating that a document has been incorporated by reference, the instant disclosure must also indicate why each of the documents is being incorporated and wherein within each of those documents the relevant text is to be located. As set forth in *Advanced Display Systems Inc. v. Kent State University* (Fed. Cir. 2000) 54 USPQ2d at 1679:

> Incorporation by reference provides a method for integrating material from various documents into a host document--a patent or printed publication in an anticipation determination--by citing such material in a manner that makes it clear that the material is effectively part of the host document as if it were explicitly contained therein. *See*

> *General Elec. Co. v. Brenner*, 407 F.2d 1258, 1261-62, 159 USQP 335, 337 (D.C. Cir. 1968); *In re Lund*, 376 F.2d 982, 989, 153 USPQ 625, 631 (CCPA 1967). **To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents.** *See In re Seversky*, 474 F.2d 671, 674, 177 USPQ 144, 146 (CCPA 1973) (providing that incorporation by reference requires a statement "clearly identifying the subject matter which is incorporated and where it is to be found"); *In re Saunders*, 444 F.2d 599, 602-02, 170 USPQ 213, 216-17 (CPA 1971) (reasoning that a rejection or anticipation is appropriate only if one reference "expressly incorporates a particular part" of another reference); *National Latex Prods. Co. v. Sun Rubber Co.*, 274 F.2d 224, 230, 123 USPQ 279, 283 (6th Cir. 1959) (requiring a specific reference to material in an earlier application in order to have that material considered a part of a later application); *cf. Lund*, 376 F.2d at 989, 13 USPQ at 631 (holding that **a one sentence reference to an abandoned application is not sufficient to incorporate from the abandoned application into a new application**). (Emphasis added.)

Accordingly, the cited documents, are still deemed to be improperly incorporated by reference and cannot therefore be relied upon for enabling the instant disclosure.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4,6-19,44-47,53-55 and 57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision of *Vas-Cath Inc. v. Mahurkar* 19 USPQ2d 1111 (CAFC, 1991):

> This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 USC 112, first paragraph, requires a "written description of the

> invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the "applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed*.

4. The amendment of claim 1, the sole independent claim, has resulted in the introduction of new matter into the claim. For convenience, claim 1 has been reproduced below.

> **1. (Amended Four Times) A composition, comprising two biopolymers, wherein:**
>
> **the first biopolymer is linked to an insoluble support by a reversible linkage; and**
>
> **the second biopolymer is linked to the first biopolymer by a reversible linkage, wherein the linkage between the insoluble support and the first biopolymer is a trityl linkage and the linkage between the first biopolymer and the second biopolymer is [formed through a trityl derivative,] a chelate complex or a photocleavable functionality.**

5. The term "biopolymers" has been interpreted as encompassing any organic molecule. Support for this broad interpretation is based in part on page 5, line 14, which defines biopolymers as being "organic molecules, including [but not limited to] nucleic acids, peptides, [and] polypeptides."

6. Page 3 of the response received 15 April 2003, hereinafter the response, directs attention to "page 8, line 13, through page 9, line 3 and claim 5 as originally filed," as providing support for the amendments to the claims.

7. Page 8, second paragraph, has been found to contain reference to "trityl group," however, the phrase was used in the context of "oligo his tail or poly his tail." Claim 5, as filed, also has

not been found to provide support for the presently claimed invention. For convenience, claim 5 has been reproduced below.

> 5. A composition according to claim 1, wherein the at least one reversible linkage is formed through a trityl derivative, a chelate complex, a hydrophobic interaction or a photocleavable functionality.

While claim 5 is found to provide support for the a "reversible linkage" that is a "trityl derivative," it lacks the clarity of description that would support a biopolymer where a first biopolymer is reversibly linked to a support through such a means and where a second biopolymer is also linked through either "a chelate complex or a photocleavable functionality." It would appear that applicant is relying upon satisfaction of the written description requirement through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

> Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

8. Further, even if the sections of the original disclosure that applicant has directed attention towards as providing support for the claimed invention did provide support for the new limitation, a position that the Office does not concede, it is noted with particularity that the paragraph that references trityl linkages is directed not generically towards biopolymers, but to "oligo his tail or poly his tail." Accordingly, and in the absence of convincing evidence to the contrary, the specification as originally filed does not provide support for the new language introduced into the claims.

9. Claims 1-4, 6-20, 22-28, 44-47, and 53-55 and 57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

10. The term "biopolymers" has been interpreted as encompassing any organic molecule. Support for this broad interpretation is based in part on page 5, line 14, which defines biopolymers as being "organic molecules, including [but not limited to] nucleic acids, peptides, [and] polypeptides."

11. Claims 1-4, 6-20, 22-28, 44-47, and 53-55 and 57 are drawn to compositions that are comprised of biopolymers which are further defined as being the following:

a. "nucleic acid and a polypeptide" (dependent claim 4);

b. "polypeptides" (claim 3), which is further defined in claim 12 as being "an antibody, enzyme, receptor and peptide;"

c. "deoxyribonucleic acid (DNA), ribonucleic acid (RNA) and analogs or mimetics of DNA or RNA" (claim 11);

d. "an enzyme" (claim 53) which is further defined as being "an alkaline phosphatase" (claim 54) and "bacterial alkaline phosphatase (BAP)" (claim 55); and

e. where the first biopolymer is "a nucleic acid, enzyme, receptor [or a] peptide" (claim 57).

12. The aspect of defining a biopolymer as being a nucleic acid (including DNA, RNA, analogs or mimetics of DNA or RNA), as well as being a polypeptide, etc., does not satisfy the written description requirement. *Enzo Biochem Inc. v. Gen-Probe Inc.* (Fed. Cir. 01-0123; April 2002). It is not enough that certain undisclosed embodiments may be obvious when the disclosure is coupled with what was known in the art at the time of filing (*Lockwood*), the specification must provide an adequate written description of the invention and for purposes of examination, the invention is what ever is being claimed. *Vas-Cath Inc. v. Mahurkar* 19 USPQ2d 1111 (Fed. Cir. 1991). Additionally, the defining one of the biopolymers as being a particular enzyme does not provide an adequate written description of the required second biopolymer where, as seen in claim 14 is a nucleic acid.

13. Claim 6 defines the insoluble support as being selected from a group consisting of a flat surface, a microtiter plate, a comb, and a bead." Claim 7 further defines these supports as being "a silicon wafer, glass plate, metal, plastic, film, and composites thereof with pits or wells" which are defined further as comprising inorganic material selected from the group consisting of "silica, Controlled Pore Glass (CPG), plastic, metal, cellulose, agarose and dextran cross-linked with epichlorohydrin" (claim 8). Upon review of the disclosure it is noted that there are but four prophetic examples and of which only example 3 (page 15) is most relevant to the claimed invention. Here it is readily seen that a "bead" of some undisclosed type is contemplated for use. The suggestion in a prophetic example does not reasonably suggest that applicant was in

possession of the genus of compositions now being claimed. While literal support may be found in the claims for certain embodiments, the specification does not provide an adequate written description of compositions where all or even some of these requisite elements are combined.

Response to argument

14. At page 6 of the response applicant asserts, "it is not necessary to include in the specification that which those of skill in the art know." This argument has been fully considered and has not been found persuasive. While applicant can rely upon that which was known in the art at the time the invention was filed in fulfilling the enablement requirement, applicant cannot trust in obviousness or skill in the art in satisfying the written description requirement of 35 USC 112, first paragraph.

15. At page 5, last paragraph of the response, "Applicant respectfully submits that recitation of any specific biopolymers in he specification is not necessary because it is the particular linked arrangement of biopolymers that constitutes the claimed subject matter of the instant claims." This argument has not been found persuasive as applicant is in effect claiming any and all nucleic acids, proteins, receptors, immunoglobulins, mimetics, etc., both known and unknown. While applicant has provided a description of a linkage, the specification has not been found to set forth in sufficient detail the first and second biopolymers that are bound by said linkages such that the specification reasonably suggests that applicant was in possession of the genera of compounds encompassed by the claims.

16. Accordingly, and in the absence of convincing evidence to the contrary, the rejection is maintained.

17. Claims 1-19, 44-47, and 53-56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Aside from providing an adequate written description of the invention, the specification must also enable the use of the invention. As presently worded, the claims encompass a vast multitude of compositions yet the specification does not set forth in sufficient detail just how one is to differentiate between those embodiments that work and those that will not work. The specification teaches at page 1 that the invention is important to the area of reversibly linking biomolecules where it can be used in "DNA sequencing, DNA diagnostics, nucleic acid amplification, Polymerase and Ligase Chain Reactions (PCR, LCR), hybridization experiments and solid phase biochemistry." At page 3 of the disclosure applicant states that "[b]y combining this reversible concept with other reversible or irreversible linkages, novel biochemical formats including diagnostic assays are possible in which favorable solid phase procedures are coupled with sensitive detection principles." The specification, however, does not teach in sufficient detail just how these multitudinous compositions are to be used in any one of these contemplated methods, much less enable all compositions in all methods. The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

> " '[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.' *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable

> correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').
>
> *****
>
> "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (starting, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. "It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (Emphasis added)

Accordingly, and in the absence of convincing evidence to the contrary, the specification has not been found to enable the use of the claimed compositions.

Response to arguments

18. Acknowledgement is made of where applicant has directed attention to other documents, including foreign and US patents. While applicant asserts at page 6, first paragraph, that from these documents that "a skilled artisan would be able to recognize what biopolymers can be used," the specification must also enable the use of said biopolymers. It is not enough that a

skilled artisan would recognize that a particular compound would be useful, the specification must set forth in sufficient clear and exacting terms just how the myriad compounds are to be used in a reproducible manner. Such full, clear, concise, and complete disclosure has not been found within the four corners of the original application.

19. It is further noted that the specification does not instruct the skilled artisan as to how methods disclosed in these prior art documents are to be modified such that the claimed compositions of matter (and related method of manufacturing said compositions) can be produced, much less used in any given assay.

20. Page 29 of the response asserts:

> The [prior art] references were cited to show the art for use of reversibly linked biopolymers. None of the references cited in the previous response were provided in support of the written description requirement. Applicant respectfully brings it the Examiner's attention that the references were not cited to provide prior art methods that can be modified to arrive at claimed compositions or methods. They were provided in support of the argument that at the time of the effective filing date of this application and before, a skilled artisan knew how to use reversibly linked biopolymers in DNA sequencing, DNA diagnostics, nucleic acid amplification, Polymerase and Ligase Chain Reactions (PCR, LCR), hybridization experiments and solid phase biochemistry.

While the Office appreciates applicant's assertions that the prior art documents are not to be relied upon for satisfaction of either written description or enablement requirements, such does not lessen the need for the instant disclosure to set forth in such "full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the" the invention. The specification presents the following four examples:

Pages 14-15:

Example 1 BAP-his$_6$ Fusion Protein

Page 15:

Example 2 Dephosphorylation of DNA Fragments with Solid Phase Bound BAP-his$_6$

Pages 15-16

Example 3 Detection of LCR Products in Microtiter Filter Plates

Page 16

Example 4 Sequence Specific Detection of PCR Fragments

A careful review of these four examples fails to locate any specific reaction conditions under which the assays are to be preformed, much less a detailed description as to how the full genera of compositions are to be made and used in a reproducible manner. While agreement is reached in that one does not need to disclose that which was well known in the art at the time of filing, such does not relieve applicant from fully enabling that, which is claimed. As shown above, the claims encompass a virtually incalculable number of compounds/compositions where the constituents are known as well as unknown. The specification fails to set forth in sufficient detail just how these species are to be produced and used. While applicant has asserted that the skilled artisan would be able to recognize these that are useful, the specification has not set forth a reproducible procedure whereby the public is enabled to both make and use these

compositions, even if they could somehow surmise that certain ones would, or could b useful. Seemingly applicant is trusting in the skill of the public to enable the making and use of the claimed compositions. Such shifting of the burden of enablement is improper and unfair as it is applicant, not the public that must fully enable the breadth of the scope of claims for which protection is being sought. Such has not happened here. For the above reasons, and in the absence of convincing evidence to the contrary, the rejections are maintained.

Claim Rejections - 35 USC § 103

21. In response to the amendment to the claims, the rejection of claims under 35 USC 103(a) has been withdrawn.

Conclusion

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

23. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

25. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

26. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS